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14. ABSTRACT Significant reductions in quality of life and cognitive function are experienced by women with breast cancer receiving adjuvant chemotherapy. These decrements can be identified in some women even several years following treatment. The majority of relevant research has been based on retrospective data in women with breast cancer. Moreover, current estimates suggest that 25% of breast cancers will be diagnosed in women under age 50, and very little data are available regarding younger women's cognitive function and quality of life during chemotherapy. The goal of the proposed study is to examine change in cognitive function and quality of life in 30 pre-menopausal women with breast cancer receiving chemotherapy. To determine if accelerated menopause is associated with change in cognition and quality of life, serum hormone levels, measures of cognitive function, quality of life variables, and symptoms of depression will be assessed. Measures will be collected at baseline before the initiation of chemotherapy, prior to the third cycle of chemotherapy, and following completion of chemotherapy, but prior to any additional treatment. A better understanding of the association between chemotherapy and quality of life is essential to provide appropriate preventive approaches and interventions aimed at maximizing the quality of life and health of young women diagnosed with breast cancer.

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Introduction:

Breast cancer affects more than 200,000 women each year in the United States (1), and most women diagnosed at an early stage have potentially curable disease. The 5-year survival rate for those diagnosed with localized breast cancer has increased from 80% in the 1950's to 98% in 2000 (2). Between 1990 and 2000, the mortality rate from breast cancer decreased by 2.3% annually. Decreases were most impressive in women under age 50, for whom mortality rates decreased by 3.7%.

Owing to the improved survival associated with administration of adjuvant chemotherapy and/or radiation therapy, the majority of women diagnosed with breast cancer will receive some type of adjuvant treatment (3). Impairment in neurocognitive function can accompany chemotherapy with deficits including memory loss, difficulty with concentration, difficulty learning new material, reading comprehension, distractibility, difficulty in performing multiple tasks (multi-tasking), altered visual/spatial orientation, verbal fluency, and the ability to work with numbers (4). Adult cancer survivors also report persistent changes in cognitive function following chemotherapy (5). The President's Cancer Panel (1999) identified cognitive deficits associated with cancer treatment as having a dramatic negative impact on quality of life; the Panel cited cognitive deficits and quality of life as problems that should be addressed both clinically and in the research arena.

Research on the impact of chemotherapy on cognitive function can be traced to the early 1980's. This research produced mixed results regarding the impact of therapy on the development of cognitive deficits (6-9). More recently, studies have revealed relationships among cognitive deficits, chemotherapy receipt, and diminished quality of life. However, questions remain regarding the neurotoxic impact of chemotherapy: Are the problems acute or chronic? Does the type and duration of therapy make a difference? How does chemotherapy affect the central nervous system? Does undergoing an accelerated menopause and change in the hormonal milieu associated with chemotherapy relate to cognitive change? Do other psychological factors influence the extent of cognitive decline? Does the stage of disease influence the severity or duration of symptoms? The proposed research will attempt to address some of these unanswered questions, specifically focusing on evaluating change in cognitive function and quality of life associated with cancer treatment in a sample of young breast cancer patients receiving a relatively uniform treatment regimen.

Body:

This is a hypothesis generating pilot study to explore multiple variables including cognitive function and quality of life in response to receiving adjuvant or neoadjuvant chemotherapy every two or three weeks for the treatment of breast cancer. Approximately sixty pre and peri-menopausal women with breast cancer receiving adjuvant or neoadjuvant chemotherapy every 2 to 3 weeks will be recruited to participate in this pilot study. Women will undergo a battery of psychosocial tools and have serum estradiol, FHS levels and hemoglobin values assessed. The battery of psychosocial tools and serum values will be collected at baseline, prior to the third cycle of chemotherapy, and approximately three to four weeks following completion of chemotherapy but prior to any antihormonal or radiation therapy. The battery of psychosocial tools will include measurements of cognition by the Cognitive Difficulities Scale and High Sensitivity Cognitive Screen; quality of life measured by the MOS-SF-36 and the BCPT Symptom Checklist; fatigue will measured by the FACT-An and the Brief Fatigue Inventory; Depression and Coping will be measured by the Beck Depression Index and the Brief COPE; and Hope, Optimism and Pessimism will be measured by the Hope scale, the LOT-R, and the PANAS.

- **Hypothesis:**

We predict that young women with breast cancer receiving chemotherapy will experience decrements in cognitive function and quality of life, and increases in menopausal symptoms and fatigue over the course of treatment. We also predict that deficits in cognitive function, and an increase in treatment-related symptoms and fatigue, may be associated with accelerated menopause (i.e., decline in estradiol).

- **Proposed Study Aims:**

1. Evaluate whether or not premenopausal women with breast cancer who are receiving chemotherapy will experience changes in cognitive function.
2. Explore the relationship between cognitive function and quality of life variables associated with receiving chemotherapy for breast cancer including: change in serum hormone levels (estradiol and FSH), self-reported symptoms collected on the Breast Cancer Prevention Trial Symptom Scales (Stanton et al., 2005), depressive symptoms, and anxiety.
3. Examine the relationship between fatigue, serum hemoglobin level, and cognitive function in premenopausal women with breast cancer receiving chemotherapy.
4. Suggest questions to be explored in future research in a similar population of women receiving chemotherapy for breast cancer.

To analyze these data we will use repeated measures analysis of variance, with Time as a three-level factor, to examine pre-mid-post changes in cognitive function using the Cognitive Difficulties Scale and the HSCS scales. Repeated measures analysis also will be used to assess changes in serum estradiol levels, serum hemoglobin levels, fatigue, menopausal symptoms, depressive symptoms, and quality of life measures. Follow-up paired t-tests will be conducted to determine the locus of significant effects (i.e., Time 1 to Time 2, Time 2 to Time 3, Time 1 to Time 3).

We also will evaluate the relationship between change in cognitive function (i.e., HSCS, Cognitive Difficulties Scale) and change in the following individual variables: serum estradiol levels, symptoms of fatigue, serum hemoglobin level, depressive symptoms, menopausal symptoms, and measures of quality of life. We will examine correlations of change scores (e.g., change in estradiol from Time 1 to Time 2 correlated with change in a cognitive function variable from Time 1 to Time 2), although it can be difficult to specify the source of variability accounting for the obtained relationship in correlated change scores. We also will examine partial correlations (e.g., Time 3 cognitive function correlated with Time 2 estradiol, partialling out Time 2 cognitive function). If multiple variables are found to predict change in cognitive function, we will conduct exploratory multiple regression analyses (e.g., cognitive function at Time 3 regressed on Time 2 cognitive function, estradiol, and fatigue). In these analyses, we will pay greater attention to proportion of variance accounted for by each predictor than to significance level, in light of the small sample size.

Key Accomplishments:

- Revised protocol was accepted by the Human Subjects Committee in April 2005.
- Attended and presented a poster at the DOD's Vision's of Hope Conference in Philadelphia, PA, in June 2005.
- Recruitment of subjects completed May 2006
- Study participation completed Aug 2006
    - Data collection (psychosocial assessments and serum) complete for all three time-points for subjects who have completed the study.
    - Anticipated data collection complete: October 2006.

Reportable Outcomes for the PI, Jennifer R. Klemp, MPH, MA:

- Successful Dissertation Proposal completed October 14, 2005
- Abstract submitted to the San Antonio Breast Cancer Symposium in June 2006.
- Abstract accepted to the San Antonio Breast Cancer Symposium in August 2006.
- Matched for Clinical Health Psychology Internship at Rush University Medical Center, Chicago, IL
- Anticipated poster presentation at the San Antonio Breast Cancer Symposium will contain a complete analysis and results of the study, December 16, 2006.
- Anticipated manuscript submission December 2006.
- Anticipated Dissertation Defense January 2007
- Anticipated completion of Ph.D. requirements in Clinical Psychology, Health Specialty, from the University of Kansas, Lawrence, KS: June 30, 2007.

Conclusions:

These results suggest that young women with breast cancer receiving chemotherapy perceive a significant impairment in cognitive function, but do not show significant impairment on a standardized measure, while experiencing a significant decrease in serum hormones, increase in depressive symptoms, and an overall decrease in QofL. A better understanding of the association between chemotherapy and QofL is essential to provide appropriate preventive approaches and interventions aimed at maximizing the QofL and health of young women with breast cancer.

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Appendices:

1. San Antonio Breast Cancer Symposium 2006 Abstract Submission: Abstract # 550677

2. Results, Data Tables, and Figures

29th Annual San Antonio Breast Cancer Symposium

Abstract Number: 550677

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Title: Evaluating the effects of chemotherapy on cognitive function and quality of life in pre-menopausal women with breast cancer

J R Klemp, MPH, MA[1], A L Stanton, PhD[2], B F Kimler, PhD[1] and C J Fabian, MD[1]. [1]BCPC, University of Kansas Medical Center, Kansas City, KS and [2]Psychology/Psych & Biobehavioral Sciences, UCLA, Los Angeles, California.

Body: Background: Significant reductions in quality of life (QofL) and cognitive function are experienced by women with breast cancer receiving chemotherapy. The majority of relevant research has been based on retrospective data. Current estimates suggest that 25% of breast cancers will be diagnosed in women under age 50, and little data are available regarding younger women's cognitive function and QofL during chemotherapy. The purpose of this pilot study was to evaluate the effects of accelerated menopause on measures of cognitive function, quality of life variables, and symptoms of depression in pre-menopausal women with a new diagnosis of breast cancer being treated with adjuvant or neo-adjuvant chemotherapy.

Methods: The goal of this study is to examine change in cognitive function and QofL in 20 pre-menopausal women with breast cancer receiving chemotherapy. To determine if accelerated menopause is associated with change in cognition and quality of life, serum hormone levels (E2, FSH) measures of cognitive function (High Sensitivity Cognitive Screen (HSCS), Cognitive Difficulties Scale, perception of function), quality of life variables (Breast Cancer Prevention Trials Symptom Check list, MOS-SF-36), and symptoms of depression (Beck Depression Inventory) were assessed. Measures were collected at baseline (before the initiation of chemotherapy), prior to the third cycle of chemotherapy, and following completion of chemotherapy, but prior to any additional treatment. A repeated measures analysis was used to assess changes in serum estradiol levels, serum hemoglobin levels, fatigue, depressive symptoms, and QofL measures.

Results: The median age of the pre-menopausal women with breast cancer was 43 and 70% had at least a college degree. Eighty-seven percent of subjects received dose-dense chemotherapy with an anthracycline &cyclophosphomide regimen and 50% received neo-adjuvant chemotherapy. E2 levels were significantly (p=.018, Wilcoxon Signed Ranks test) decreased from a median pre-treatment estradiol level of 67.7 pg/ml [range, 37.4-106] to a median post-treatment level of 30.5 pg/ml [range, 14.7-57.6]. Women reported an increase in symptoms associated with QofL and depression. Women also reported an increased perception of impairment within concentration and memory domains, even though this was not reflected in changes in memory HSCS subtest scores.

Conclusion: These results suggest that young women with breast cancer receiving chemotherapy perceive a significant impairment in cognitive function, but do not show significant impairment on a standardized measure, while experiencing a significant decrease in serum hormones, increase in depressive symptoms, and an overall decrease in QofL. A better understanding of the association between chemotherapy and QofL is essential to provide appropriate preventive approaches and interventions aimed at maximizing the QofL and health of young women with breast cancer.

Results

Sample Characteristics and Study Recruitment

As depicted in Table 2, participants were 20 pre-menopausal women with a recent diagnosis of breast cancer, who had not yet received chemotherapy at study entry, but had undergone a biopsy and/or definitive surgery and their planned treatment included chemotherapy (Adrimycin & Cytoxan, Epirubicin & Cytoxan, Herceptin or Carboplatinum + Taxotere). Thirty women were invited to participate in the study and were provided with a written overview of the clinical trial. Twenty women agreed to participate, signed an informed consent, began and completed the study, and their results are presented in this analysis. Reasons why some women opted not to participate in the study included timing of their initial treatment (e.g. started treatment the same day as their clinic visit) or travel distance to and from the cancer center. The median age of the study population was 43 years old (range 28-51), the majority of the subjects were white (85%), 80% of the subjects had at least a college education, and 85% were working full or part-time.

Effects on Cognitive Functioning

Repeated measures analyses of variance revealed no significant effect of treatment on objective cognitive functioning measured by the HSCS (Table 3). However, the memory subscale of the HSCS demonstrated a significant improvement in memory between baseline and post-treatment assessments p=.042. The subjective measure of cognitive functioning, the CDS, also did not demonstrate a significant decline in cognitive functioning (F (1,19) = 1.07, p=.31).

By clinical interview at the off-study visit, subjects reported difficulty with word finding, memory, and speed of processing. Subjective changes in cognitive functioning also emerged from the BCPT Cognitive Problems scale, (F (1,19) = 8.44, p= 0.009).

Change in Serum Hormones Levels and Menopause Status

Only three subjects reported having a single menstrual period following the initiation of their chemotherapy regimen. All others stopped menstruating. Repeated measures analysis of variance revealed changes in serum hormones and hemoglobin levels over the course of treatment (Table 4). Significant decreases in estradiol and hemoglobin levels were detected. Non-significant increases were noted in testosterone and progesterone levels, and IGF1/IGFBP-3 ratios remained consistent.

Similar results were found using a paired sample t-test (i.e., Time 1 to Time 2, Time 2 to Time 3, Time 1 to Time 3). Paired sample t-test showed that estradiol from Time 1 to Time 2 (t (19) = 4.49, p = <.001), Time 2 to Time 3 (t (19) = 3.74, p= <.001), and Time 1 to Time 3 (t (19) = 5.34, p= <.001), significantly decreased. Hemoglobin levels decreased significantly from Time 1 to Time 3 (, p <.001), whereas change from Time 1 to Time 2 (t = , p=.149), and Time 2 to Time 3 (t=, p=.135, were not significant.

Quality of Life Variables

Depressive symptoms: Repeated analyses of variance detected a significant increase in depressive symptoms (Table 5) on the BDI (F (1,19) = 14.2, p <.001) over the course of treatment. Mean group BDI scores at baseline and mid-treatment were not elevated to the cutoff of 10, which is suggestive of mild clinical depression, but the post- treatment mean was over the threshold. However, 20% of subjects at baseline, 35% of subjects mid-treatment, and 55% of post-treatment subjects had a BDI score of at least 10, indicating that number of subjects had symptoms suggestive of at least mild clinical depression (Table 6). By treatment completion, 45% reported negligible symptoms and 55% reported at least mild symptoms of depression. In contrast, a non-significant increase in depressive symptoms (Tables 5 and 6) was observed on the CES-D. Mean CES-D levels were not elevated over the course of treatment, but 30% of subjects at baseline, 20% of subjects mid-treatment, and 50% of subjects post-treatment had a CES-D score of at least 16 (Radloff, 1977), the cutoff suggestive of clinical depression.

Health related quality of life: the SF-36 and the FACT were use to assess psychological functioning. Lower scores on the SF-36 reflect poorer quality of life. Table 7 provide normative data on the SF-36 subscales broken down by age (Ware, 1993, 1994). Repeated within subjects analysis of variance using the SF-36 Emotional Function scale (F(1,19)= .137, p=.716) and the SF-36 Mental Health scale (F(1,19) = .085, p=.774) did not find significant differences over the course of treatment (Table 8). Repeated analyses of variance revealed a significant negative impact on physical functioning as reported by the SF-36 Physical Functioning Scale (F (1,19) = 4.91, p <.039). Other SF-36 measures of General Health and Social Functioning, did not demonstrate a significant difference over the course of treatment. The mean baseline Mental Health summary score (Table 7) was similar to those seen by other studies of women with early-stage breast cancer (Burstein, Gelber, Guadagnoli, & Weeks, 2007) and compared to a normative data set (Ware, 1993, 1994) as depicted in Figures 1. Repeated analysis of variance using the SF-36 Physical Health Summary Scale (F (1,19) = .999, p =

.330) and the Mental Health Summary Scale (F (1,19) = .013, p = .909) did not find significant differences over the course of treatment.

The Functional Assessment of Cancer Treatment-General (FACT-G) was administered at baseline and post-treatment assessment points. Repeated measures analyses of variance revealed a significant increase in symptoms commonly associated with cancer treatment. The FACT-Fatigue subscale, the FACT-Anemia subscale, the FACT-Social Wellbeing subscale, and the FACT-Functional Wellbeing subscale, all reported a significant increase in symptoms from baseline. The FACT-General full scale reported a marginal change over the course of treatment (F (1,19) = 4.2, p =.055).

Breast cancer-related symptoms: Repeated measures analyses of variance revealed a decline in symptoms related to breast cancer measured by the BCPT Symptom Checklist (Table 10). Pair-wise comparisons revealed no significant change from Time 1 to Time 2 (t (19)= -1.69, p = .108), but significant changes from Time 1 to Time 3 (t (19) = -4.86, p = <.001), and Time 2 to Time 3 (t (19) = -4.83, p = <.001). Repeated measures of analysis of variance found an increase in subjective reports of hot flashes (F (1,19) = 33.51, p <.001). Pair-wise comparisons revealed no significant change from Time 1 to Time 2 (t (19)= -1.96, p = .065), but significant changes from Time 1 to Time 3 (t (19) = -5.79, p = <.001), and Time 2 to Time 3 (t (19) = -4.45, p = <.001).

Table 2

Study Sample Characteristics

Characteristic	**Subjects N=20 (range)**
Median Age (years)	43 (28-51)
Race: White	17
Black	1
Hispanic	2
Education: High school	4
College	14
Post-graduate	2
Employment: Not working	3
Part-time	2
Full-time	15
Marital Status: Married/Coupled	15
Single/Divorced/Widowed	5
Tumor Stage: not reported	1
I	11
II	6
III	1
IV	1
Lymph Node Status: Positive	15
Negative	5
ER/PR Status: ER+/PR+	15
ER-/PR-	5
Type of Therapy: Adjuvant	9
Neoadjuvant	11
Dosing of Therapy: Standard	7
Dose-dense	13
Tx Regimen: AC or EC	14
Taxotere + Carbo	4
Taxotere + Herceptin	2
Type of Surgery: Lumpectomy	14
Mastectomy	6

Table 3

Cognitive function at baseline, mid- and post-treatment repeated measures analyses of variance

Measure	Baseline *M (SD)*	Mid-Treatment *M (SD)*	Post-treatment *M (SD)*	F (*df=1,19)*	*p*
Cognitive Difficulities Scale	25.85 (13.98)	23.80 (14.58)	28.15 (13.66)	1.07	0.313
BCPT Cognitive Problems Scale	0.75 (.67)	0.82 (.70)	1.32 (.89)	8.44	0.009
HSCS Memory Scale	16.00 (10.55)	N/A	12.75 (7.56)	4.76	0.042
HSCS Language Scale	2.45 (2.56)	N/A	1.80 (2.50)	1.17	0.292
HSCS Attention	0.75 (1.12)	N/A	0.65 (1.04)	0.16	0.694
HSCS Self Regulation & Planning	3.00 (2.00)	N/A	1.90 (1.62)	4.04	0.059

Table 4

Within-Subjects Change in serum hormone levels over the course of treatment

Serum Measure	Baseline *M (SD)*	Mid-Tx *M (SD)*	Post-Tx *M (SD)*	*F* (*df*=1,19)	*p*
Estradiol (pg/mL)	64.79 (28.84)	41.12 (16.08)	28.68 (10.93)	28.52	<.001
Testosterone (ng/mL)	11852.79 (1688.32)	12115.41 (48.21)	12127.82 (46.75)	0.54	0.470
Progesterone (ng/mL)	14290.86 (1078.43)	14537.46 (57.65)	14551.15 (56.10)	1.22	0.284
IGF1/IGFBP3 ratio (ng/mL)	0.187 (.03)	0.180 (.04)	0.190 (.05)	0.06	0.805
Hemoglobin (Hb) (mg/dL)	12.66 (1.30)	11.90 (2.20)	11.17 (.78)	46.82	<.001

Table 5

Baseline, Mid-treatment, and post-treatment repeated measures analyses of depressive symptomology

Measure	Baseline M (*SD*)	Mid-Treatment *M (SD)*	Post-treatment *M (SD)*	F (*df* = 1,19)	*p*-value
BDI	7.7 (5.0)	8.95 (6.6)	11.65 (7.1)	14.2	<.001
CES-D	13.85 (10.98)	12.6 (11.16)	15.15 (9.5)	.527	.477

Table 6

Self-Reported Symptoms Meeting Criteria Suggestive of Clinical Depression

Depression Scale	**Baseline % (N)**	**Mid-Treatment % (N)**	**Post-Treatment % (N)**
Normal (Range 0-9)	80% (16/20)	13/20 (65%)	45% (9/20)
Beck Depression Inventory ≥ 10	20% (4/20)	35% (7/20)	55% (11/20)
Severity of BDI Depressive Symptoms			
Mild (Range 10-18)	75% (3/4)	71% (5/7)	64% (7/11)
Moderate (Range 19-29)	25% (1/4)	29% (2/7)	36% (4/11)
Severe (Range 30-63)	0	0	0
CES-D ≥ 16	30% (6/20)	20% (4/20)	50% (10/20)

Table 7

Mean (SD) scores for six variables of SF-36 by age: Normative Data

	AGE (years)		
Variable	**25-34**	**35-44**	**45-55**
Physical functioning	92.9 (13.3)	89.4 (16.1)	84.8 (18.3)
Emotional functioning	80.6 (34.0)	80.3 (33.6)	80.8 (33.6)
General Health	77.3 (18.5)	74.1 (20.3)	73.1 (19.9)
Mental Health	71.6 (15.2)	71.6 (17.8)	73.2 (18.2)
Bodily Pain	82.1 (21.1)	79.4 (22.0)	77.4 (22.3)
Social Function	87.1 (18.9)	86.7 (20.5)	87.0 (20.8)

Table 8

SF-36 Summary scales and subscales

Measure	Baseline *M* (*SD*)	Mid-Treatment *M (SD)*	Post-treatment *M (SD)*	F (*df* = 1,19)	*p*	η^2
SF-36 Physical Health Summary Score	37.23 (11.27)	41.46 (10.99)	40.65 (10.87)	.999	.330	.050
SF-36 Mental Health Summary Score	41.52 (8.33)	42.35 (6.78)	41.29 (8.22)	.013	.909	.001
SF-36 Emotional Function	43.33 (30.78)	51.67 (31.49)	40.01 (38.39)	0.137	.716	.716
SF-36 Physical Function	76.50 (24.77)	68.00 (24.73)	62.25 (25.21)	4.911	0.039	.039
SF-36 General Health	69.55 (22.21)	67.65 (20.17)	64.40 (20.73)	2.21	0.154	.154
SF-36 Mental Health	69.60 (19.0)	73.80 (18.0)	70.80 (18.5)	0.085	.774	.744
SF-36 Bodily Pain	65.30 (26.77)	66.40 (24.29)	70.35 (23.26)	0.482	.496	.496
SF-36 Social Function	29.38 (29.32)	30.00 28.79)	41.25 (26.62)	4.037	0.059	.059

Table 9

Measure of quality of life: FACT-General and subscales

Measure	Baseline M (*SD*)	Post-treatment *M (SD)*	F (*df* = 1,19)	*p*
FACT-General	84.76 (13.79)	79.76 (14.91)	4.2	0.055
FACT-Fatigue Subscale	35.73 (10.54)	29.64 (12.90)	19.23	.013
FACT-Anemia Subscale	58.55 (12.85)	49.14 (15.3)	14.95	.027
FACT-Social Wellbeing	24.68 (2.97)	23.03 (3.7)	12.60	.002
FACT-Emotional Wellbeing	16.6 (5.14)	17.59 (2.97)	1.06	.267
FACT-Functional Wellbeing	19.14 (5.36)	15.78 (4.85)	15.51	.010

Table 10

Baseline, Mid-treatment, and post-treatment repeated measures analyses of quality of life symptoms measured by the Breast Cancer Prevention Trials Checklist

Measure	Baseline M (*SD*)	Mid-Treatment *M (SD)*	Post-treatment *M (SD)*	F (*df* = 1,19)	*p*-value
BCPT Total	0.45 (.40)	0.59 (.37)	0.90 (.41)	23.64	<.001
BCPT Hot Flashes	0.35 (.52)	0.75 (.72)	1.73 (.92)	33.51	<.001
BCPT Weight Problems	0.50 (.65)	0.63 (.69)	0.98 (.83)	4.58	0.046

Figure 1

Mean Baseline SF-36 Physical and Mental Health Summary Scores between subjects, newly diagnosed BrCa patients, and a normative data set